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EXAMINER

COUNTS, GARY W

ART UNIT

PAPER NUMBER

1641

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/602,778

Applicant(s)

BAMDAD ET AL.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2002.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-204 is/are pending in the application.
- 4a) Of the above claim(s) 39-59 and 85-181 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-38, 60- 84 and 182-204 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION*****Election/Restrictions***

Applicant's election with traverse of Group I, Species (A) Beads in Paper No. 10 is acknowledged. The traversal is on the ground(s) that it is believed that a single search and examination could be carried out, without undue burden. This is not found persuasive because restriction requirements are set forth for reasons patentable distinction between each independent invention so as to warrant separate classification and search. The record set forth in the previous restriction requirement clearly indicated that the delineated inventions are in fact patentably distinct each from the other or independent from the other. The requirement is still deemed proper and is therefore made **FINAL** for reasons of record.

***Priority***

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

**Claim Objections**

Claim 189 is objected to because of the following minor informalities.

Claim 189 depends from "claim 104" it appears that it should depend from --claim 184--.

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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2. Claims 1-38, 60-84 and 182-2104 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because the body of the claim lacks a preamble and it is unclear what the method is directed to.

Claim 1, line 2 the recitations "allowing" and "the ability" is vague and indefinite. The recitations appear to be mental steps and no actual step is provided which shows how the colloidal particle is given this ability to become immobilized.

Claim 1, line 2 "the ability to become immobilized" is vague and indefinite. Is the colloid particle immobilized to a non-colloidal structure or not?

Claim 6, the recitation "allowing" is vague. It is unclear what applicant intends. See deficiencies throughout the claims.

Claim 6, the recitation "plurality of colloid particles" is vague and indefinite. Are there many different colloid particles or are there many of the same colloid particles? See also deficiency found in claim 22.

Claim 9, lines 2 and 3 "adapted" is vague and indefinite. It is unclear how the biological or chemical agent is adapted for linkage to the non-colloidal structure. See deficiencies throughout the claims.

Claim 9, line 4 "via" is vague and indefinite. It is unclear what the term encompasses. See deficiencies throughout the claims. Also the phrase "via" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

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Claim 21, line 10 "the target" there is insufficient antecedent basis for this limitation.

Claim 22, line 16 "suspected of having the ability to bind to each other" is vague and indefinite. Can the agents and the binding partners bind to each other or not? See deficiencies throughout the claims.

Claim 22, line 14 "plurality of binding partners" is vague and indefinite. Are there many different binding partners or are there many of the same binding partners.

Claim 23, line 24 "versus" is vague. It is unclear what applicant intends. It is suggested to change the recitation to --as compared to--. See deficiencies throughout the claims.

Claim 25, line 31 "exposing" is vague and indefinite. It is unclear what applicant intends. Are the beads contacted with a first set of particles or are they brought into close proximity of the first set of particles? See deficiencies throughout the claims.

Claim 31, line 26 "chelate coordinating a metal" is vague. It is unclear how the chelate coordinates the metal.

Claim 35, line 14 "vs." is vague. It is unclear what applicant intends. It is suggested to change the recitation to "as compared to". See deficiencies throughout the claims.

Claim 63, line 2 "having the ability" is vague and indefinite. Does the enzyme cleave the agent or binding partner or not?

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Claim 71 is vague and indefinite because it is unclear what applicant is trying to encompass. Applicant is trying to form a linkage in the presence of an enzyme which cleaves?

Claim 71, line 5 "an entity" is vague and indefinite. It is unclear what applicant is referring to. There is no definition provided for the recitation in the specification.

Claim 71, line 6 "having the ability" is vague and indefinite. Does the enzyme cleave the entity or not?

Claim 71, line 7 the recitation "moderation" is vague and indefinite. It is unclear what applicant intends. Does the candidate drug increase the ability of the enzyme to cleave the entity or does it decrease the ability of the enzyme to cleave the entity or does it inhibit it completely. See also deficiency found in claim 75.

Claim 182, line 5 "an article" is vague and indefinite. It is unclear what applicant is referring to. There is no definition provided in the specification for this recitation.

Claim 182, line 8 "other first species" is vague and indefinite. It is unclear what applicant is referring to. Is applicant referring to the first molecule species or a different species.

Claim 184 "the surface" there is insufficient antecedent basis for this limitation.

Claim 188, line 126 "defect sites" is vague and indefinite. It is unclear what applicant intends.

Claim 189 "the electroactive entity" there is insufficient antecedent basis for this limitation.

Claim 192 "the surface" there is insufficient antecedent basis for this limitation.

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Claim 192 "the article" there is insufficient antecedent basis for this limitation.

Claim 197 is vague and indefinite because of the use of acronyms: i.e. EDC/NHS. Although the terms may have art-recognized meanings, it is unclear if applicant intends to claim the prior art definitions. The terms should be defined in their first instance.

### ***Claim Rejections - 35 USC § 102***

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

4. Claims 1, 6, 9, 13, 14, 19, 20, 26, 27, 29, 183, and 191 are rejected under 35 U.S.C. 102(b) as being anticipated by Ching et al (EP 0299428).

Ching et al disclose a method comprising a colloidal particle labeled first specific binding reagent which is transported to a first zone where a second reagent has been immobilized to chromatographic substrate material (non-colloidal structure) Ching et al disclose that the labeled first reagent and the analyte if present are immobilized by

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reaction with the second reagent (p. 9, lines 18-32) and a visibly detectable signal is produced. Ching et al disclose that the specific binding reagents are members of a specific binding pair consisting of a ligand and a receptor. Ching et al disclose that the reagents can be antibodies and analytes, avidin and biotin, streptavidin and antibiotin (p. 18, lines 27-37).

5. Claims 1, and 183 are rejected under 35 U.S.C. 102(b) as being anticipated by Olsen et al (US 4,853,335).

Olsen et al disclose a method for detecting an antigen in a biological specimen. Olsen et al disclose a colloidal gold labeled ligand or antiligand reagent or antiligand bound solid phase particles which are combined with a sample. Olsen et al disclose that the particles are captured on a membrane (non-colloidal structure) and visually inspected for color (col 2, line 67 – col 3 line 15).

6. Claims 1, 6, 9-12, 22, 26, 28, 35-38 and 183 are rejected under 35 U.S.C. 102(b) as being anticipated by Hansen et al (US 5,589,401).

Hansen et al disclose a method for the simultaneous determination of one or more analytes in a fluid. Hansen et al disclose polymeric microspheres (non-colloidal structure) coated with a first binding molecule, colloid particles coated with a second binding molecule, and an analyte that is complementary to both binding molecules. In the presence of the analyte a complex is formed and the colloid particle is immobilized relative to the polymeric microsphere (col 3, lines 59-64). Hansen et al disclose that the polymeric microsphere is a polystyrene microsphere (col 7, lines 18-19). Hansen et al disclose the use of a plurality of microspheres and reagents which allow for the



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determination of a plurality of analytes (col 9, line 64 – col 10, line 22). Hansen et al disclose that one can analyze concurrently multiple analytes by using the appropriate reagents (col 9, line 64 – col 10, line 22)

7. Claims 1-3, 6-9, 18-20, 32, 33 183, 184 and 191 rejected under 35 U.S.C. 102(e) as being anticipated by Sigal et al (US 6,319,670).

Sigal et al disclose a method comprising colloidal particles having one or more assay ligands immobilized on its out surface. Sigal et al also disclose that the colloidal particles have plurality of electrochemiluminescent moieties (auxiliary signaling entity) immobilized on the particle. Sigal et al disclose assays for an analyte of interest comprising forming a composition of the sample and one or more colloidal particles, incubating the composition to form a complex and causing the complex to bind to an assay-ligand immobilized on an electrode (non-colloidal structure) and determining the presence of the reactants (col 2, line 47 – col 3, line 5). Sigal et al disclose that the assay-ligands include proteins (oligopeptides, polypeptides) and nucleic acids (col 3, lines 32-56). Sigal et al disclose that the colloidal particles may be comprised of gold.

8. Claims 1, 6, 9, 71, 74, 75 and 183 are rejected under 35 U.S.C. 102(e) as being anticipated by Virtanen et al (US Patent 6,342,349).

Virtanen et al disclose an immunoassay method comprising colloid particles (col 37, lines 40-42), which are immobilized to a substrate (non-colloidal structure). Virtanen et al disclose that the colloid particle and the substrate (non-colloidal structure) are exposed to cleavable spacer molecules (entity), which comprise cleavage sites. (see figures 1 and 3). Virtanen et al disclose that the cleavable spacer molecules bind to

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both the colloid particle and to the non-colloidal structure. Virtanen et al disclose that enzymes can be used as cleavage reagents by incorporating into the spacer a moiety that serves as the substrate (enzyme substrate) for the given enzyme (col 34, lines 15-17). Virtanen et al disclose that the analyte can be a drug candidate (col 55, line 53 – col 56, line 67). Virtanen et al disclose that the cleavable spacer molecules also comprise antibodies specific for the analyte of interest. Virtanen et al disclose that when the analyte (drug candidate) is present it binds to the antibody and prevents the chemical cleaving agent (enzyme) from cleaving the colloid particle from the surface (col 18, lines 1-16). Virtanen et al disclose that the presence and absence of the colloid particle may then be detected.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al (US 6,319,670) in view of Forrest et al (EP 0142301).

See above for teachings of Sigal et al.

Sigal et al differ from the instant invention in failing to disclose the signaling entity comprises a ferrocene.

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Forrest et al disclose the use of Ferrocene as a label in electrochemical specific-binding assays. Forrest et al disclose that the use of this label avoids radioactive labels and provides a simple, rapid, sensitive and specific assay method (page 2).

It would have been obvious to one of ordinary skill in the art to incorporate a ferrocene label as taught by Sigal et al into the method of Forrest et al because Forrest et al shows that the use of this label avoids radioactive labels and provides a simple, rapid, sensitive and specific assay method (page 2).

11. Claims 15 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al (US 5,589,401) in view of Gowowski et al (6,413,770).

See above for teachings of Hansen et al.

Hansen et al differ from the instant invention in failing to disclose the biological or chemical agent is a drug candidate, and the binding partner is a target of the drug candidate wherein the non-colloidal structure is a bead.

Godowski et al disclose immobilized drug candidates and binding partners for the drug candidates (col 46, lines 35-67).

It would have been obvious to one of ordinary skill in the art to incorporate drug candidates and their binding partners as taught by Godowski et al into the method of Hansen et al because Godowski et al shows that the use of these reagents provides for screening assays.

12. Claims 15 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al (US 6,319,670) in view of Godowski et al (US 6,413,770).

See above for teachings of Sigal et al.

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Sigal et al differ from the instant invention in failing to teach the biological or chemical agent is a drug candidate and the binding partner is a target of the drug candidate wherein the non-colloidal structure is surface of an essentially planar substrate.

Godowski et al disclose immobilized drug candidates and binding partners for the drug candidates (col 46, lines 35-67).

It would have been obvious to one of ordinary skill in the art to incorporate drug candidates and there binding partners as taught by Godowski et al into the method of Sigal et al because Godowski et al shows that the use of these reagents provides for screening assays.

13. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ching et al (EP 0299428) in view of Charych et al (US 6,001,556).

See above for teachings of Ching et al.

Ching et al differ from the instant invention in failing to teach allowing the colloidal particle the ability to fasten to the non-colloidal structure in the presence of a candidate drug for interruption of binding of the ligand.

Charych et al disclose a competitive assay in which a drug candidate is introduced into a system containing a receptor and its reciprocal binding partner.

Charych et al disclose that if the drug binds to the receptor or modifies the binding partner's binding capacity, there is a decrease in the signal (col 20, lines 1-40).

Charych et al disclose that this provides for the development and improvement of drugs

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by observing competitive inhibition of natural binding events between all surfaces or binding sites and their natural bioactive ligand.

It would have been obvious to one of ordinary skill in the art to incorporate candidate drugs and their reagents as taught by Charych et al into the method of Ching et al because Charych et al shows that that this provides for the development and improvement of drugs by observing competitive inhibition of natural binding events between all surfaces or binding sites and their natural bioactive ligand.

14. Claims 23 -25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hansen et al (US 5,589,401) in view of Virtanen et al (US 6,342,349).

See above for teachings of Hansen et al.

Hansen et al differ from the instant invention in failing to teach the biological or chemical agents are drug candidates and the binding partners are targets of the drug candidates.

Virtanen et al disclose the use of drug candidates and antibodies for the drug candidates. Virtanen et al also disclose the use of multi-well plates. The use of these reagents provide for coupling of antibodies for the ready adaptation of standard immunoassay chemistries and immunoassay geometries.

It would have been obvious to one of ordinary skill in the art to incorporate candidate drugs and antibodies as taught by Virtanen et al into the method of Hansen et al because the use of these reagents provide for coupling of antibodies for the ready adaptation of standard immunoassay chemistries and immunoassay geometries.

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Claims 30, 31, 182, 185-188, 190, 192-196, and 198-204 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al (US 6,319,670) in view of Bamdad et al (US 5,620,850).

See above for teachings of Sigal et al.

Sigal et al differ from the instant invention failing to teach that the agent or binding partner is adapted for linkage to the non-colloidal structure or particle by a metal binding tag/metal/chelate linkage. Sigal et al also fail to teach the agent or binding partner carries immobilized thereto a chelate coordinating metal, and at least one of the agent or binding partner is derivatized with a polyamino acid tag. Sigal et al also differ from the instant invention in failing to disclose the non-colloidal structure comprises an article defining a surface and a self-assembled monolayer formed on the surface of the article.

Bamdad et al disclose metal binding tag/metal/chelate linkers and biomolecules derivatized with a polyamino acid tag, which coordinate the metal ion (see columns 5-8). Bamdad et al disclose that the use of such tags provide an easily synthesized chemical species that readily adheres to a surface and that facilitates surface immobilization of a binding partner of a molecule desirably captured at the surface with a high degree of sensitivity and minimal to zero non-specific binding. Bamdad also disclose an article including a solid phase that has a surface and that a self-assembled mixed monolayer formed of a first species and a second species is adhered to the surface (col 5, lines 9-67). Bamdad et al disclose self-assembled mixed monolayer provides an article with a

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surface having a high degree of sensitivity for a biological molecule (col 2, lines 60-62).

Bamdad et al also disclose that biotin can be combined with protein reagents.

It would have been obvious to one of ordinary skill in the art to incorporate tags as taught by Bamdad et al into the method of Sigal et al because Bamdad et al shows that the use of such tags provide an easily synthesized chemical species that readily adheres to a surface and that facilitates surface immobilization of a binding partner of a molecule desirably captured at the surface with a high degree of sensitivity and minimal to zero non-specific binding.

It also would have been obvious to one of ordinary skill in the art to incorporate an article and self-assembled monolayer as taught by Bamdad et al into the method of Sigal et al because Bamdad et al shows that such an article provides a surface that has a high degree of sensitivity for a biological molecule.

It also would have been obvious to one of ordinary skill in the art to incorporate a self-assemble monolayer as taught by Bamdad et al onto the colloidal particle of Sigal et al because Bamdad et al shows that this monolayer provides a surface with a high degree of sensitivity for a biological molecule.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al. (US 6,319,670) in view of Altieri et al (US Patent 6,346,389).

See above for teachings of Sigal et al.

Sigal et al differ from the instant invention in failing to teach the binding partner is adapted for linkage to the particle by glutathione/glutathione-s-transferase ligand interaction.

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Altieri et al disclose glutathione-s-transferase fusion proteins which are immobilized onto a glutathione substrate. Altieri et al disclose that this immobilization allows for the separation of protein-protein complexes from uncomplexed forms, as well as to accommodate automation of an assay (col 10, lines 9-36).

It would have been obvious to one of ordinary skill in the art to incorporate glutathione-s-transferase fusion proteins and glutathione substrates as taught by Altieri et al into the method of Sigal et al because Altieri et al disclose that this immobilization allows for the separation of protein-protein complexes from uncomplexed forms, as well as to accommodate automation of an assay.

16. Claims 73 and 77 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al (US 6,319,670) in view of Virtanen et al (US 6,342,349).

See above for teachings of Sigal et al.

Sigal et al differ from the instant invention in failing to teach an entity adapted for linkage both to the colloid particle and to the non-colloidal structure in the presence both of an enzyme having the ability to cleave the entity and a candidate drug for moderation of activity of the enzyme.

Virtanen et al disclose that the cleavable spacer molecules bind to both the colloid particle and to the non-colloidal structure. Virtanen et al disclose that enzymes can be used as cleavage reagents by incorporating into the spacer a moiety that serves as the substrate (enzyme substrate) for the given enzyme (col 34, lines 15-17).

Virtanen et al disclose that the analyte can be a drug candidate (col 55, line 53 – col 56, line 67). Virtanen et al disclose that the cleavable spacer molecules also comprise



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antibodies specific for the analyte of interest. Virtanen et al disclose that when the analyte (drug candidate) is present it binds to the antibody and prevents the chemical cleaving agent (enzyme) from cleaving the colloid particle from the surface (col 18, lines 1-16). Virtanen et al disclose that the cleavable spacer molecules provide particular advantages for immunoassays. The immunoassay is both fast and sensitive; diffusion of antibodies through a fluid phase is obviated (col 19, lines 19-31).

It would have been obvious to one of ordinary skill in the art to incorporate cleavable spacer molecules, enzyme reagents and candidate drugs as taught by Virtanen et al into the method of Sigal et al because Virtanen et al shows that the cleavable spacer molecules provide particular advantages for immunoassays. The immunoassay is both fast and sensitive; diffusion of antibodies through a fluid phase is obviated (col 19, lines 19-31).

17. Claim 197 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sigal et al in view of Bamdad et al (US 5,620,850) as applied to claims 1-3, 6-9, 18-20, 30-33, 182-188, 190, 192-196 and 198-204 above, and further in view of Ruoslahti et al (US 6,180,084).

See above for teachings of Sigal et al and Bamdad et al.

Sigal et al and Bamdad et al differ from the instant invention in failing to teach EDC/NHS coupling chemistry.

Ruoslahti et al disclose that the use of EDC and NHS in combination is commonly used for conjugation in order to increase yield of conjugate formation.

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It would have been obvious to one of ordinary skill in the art to incorporate the use of EDC/NHS into the modified method of Sigal et al because Ruoslahti et al show that the use of EDC and NHS in combination is commonly used for conjugation in order to increase yield of conjugate formation.

### ***Allowable Subject Matter***

18. Claims 60-70, 72, 76 and 78-84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

19. The following is a statement of reasons for the indication of allowable subject matter: the prior art neither teaches nor suggests a method comprising a non-colloidal structure is a magnetic bead and a colloid particle comprises an auxillary signaling entity wherein the colloid particle is immobilized to the magnetic bead.

The closest reference is Hansen et al (US 5,589,401) Hansen et al disclose homogeneous immunoassay methods comprising non-colloidal polymeric beads, which form a complex with colloid particles. Hansen et al does not disclose or suggest the use of magnetic particles nor does Hansen et al disclose the colloid particles comprise an auxillary signaling entity.

### ***Conclusion***

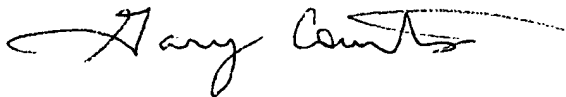
No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Gary W. Counts  
Examiner  
Art Unit 1641  
August 26, 2002



CHRISTOPHER L. CHIN  
PRIMARY EXAMINER  
GROUP 1800 / 641